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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,672	12/14/2001	Kiyotaka Nishikawa	C01123/70001	9573

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EXAMINER	
SHIBUYA, MARK LANCE	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 06/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/017,672	NISHIKAWA ET AL.	
	Examiner	Art Unit	
	Mark Shibuya	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,9,13,21,26,27,30,36,38,39,42,46,48,52,55,60 and 64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *-4, 9, 13, 21, 26, 27, 30, 36, 38, 39, 42, 46, 48, 52, 55, 60 & 64* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-4, 9, 13, 21, 26, 27, 30, 36, 38, 39, 42, 46, 48, 52, 55, 60 and 64 are pending and subject to the instant Requirement for Restriction/Election. The applicant is invited to note that the Preliminary Amendment, filed 8/7/2002, at p. 1, directed the cancellation of claim 27, but provided an amended claim 27 in the body of the same Preliminary Amendment (see p. 2).

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 9 and 13, drawn to methods for determining an amino acid sequence binding motif for a phosphorylation site of a kinase comprising contacting the kinase with a peptide library and determining an amino acid sequence motif for a binding site of the kinase, classified in class 435, subclass 7.1.

II. Claims 21 and 64, drawn to a kinase binding molecule comprising a binding motif identified according to the method of claim 1, classified in class 530, subclass 300.

III. Claim 26, drawn to a method for inhibiting phosphorylation of proteins by a kinase by contacting the kinase with the kinase binding molecule of claim 21, classified in class 435, subclass 194.

IV. Claim 27, drawn to a method for treating a condition by administering the kinase binding molecule of claim 21, classified in class 514, subclass 2.

V. Claims 30 and 36, drawn to a kinase inhibitor comprising a binding motif as identified by the method of claim 1, wherein the single non-degenerate phosphorylatable amino acid is replaced by an amino acid that cannot be phosphorylated, classified in class 530, subclass 300.

VI. Claims 38 and 46, drawn to a method for inhibiting phosphorylation of proteins by a kinase using the kinase inhibitor of claim 30, and further wherein the kinase is a ZAP-70 kinase, classified in class 435, subclass 194.

VII. Claims 39, 48 and 55, drawn to a method for treatment comprising administering the kinase inhibitor of claim 30, and further wherein the kinase is a ZAP-70 kinase, classified in class 514, subclass 2.

VIII. Claim 42, drawn to a method for validating a kinase as a target for inhibition in the treatment of a condition wherein a biological sample containing a suspect kinase is contacted with a peptide comprising the binding motif of claim 1 and determining the effect of the binding motif on one or more biological processes, classified in class 435, subclass 194.

IX. Claim 52, drawn to a method for inhibiting transcription mediated by a ZAP-70-responsive promoter using an inhibitor of claim 30, classified in class 435, subclass 194.

X. Claim 60, drawn to a method for identifying a kinase inhibitor comprising competing a known kinase-binding inhibitor with a candidate kinase inhibitor, wherein the known kinase inhibitor or candidate kinase inhibitor

are identified by the method of claim 1, classified in class 435, subclass 194.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions of Group I and Groups II, V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the products may be identified by a materially different method such as providing a labeled potential kinase binding peptide of known structure and ascertaining whether that peptide binds to a kinase enzyme using saturation binding experiments and Scatchard analysis.

Inventions of Groups II, V and the Inventions of Groups III, IV, VI-X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of Groups II and V may be used in methods of diagnosing diseases involving kinases, which is a different use from the processes of Groups III, IV, VI-XI, including the methods of inhibiting kinases of Groups III, VI, IX, and the methods of treatment of Groups IV and VII.

Inventions of Group II and the inventions of Group V are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is deemed to be useful as the peptide motifs of Group II bind to kinases and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Inventions of Group I, and the Inventions of Groups III, IV, VI-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions of Group I are directed to identifying kinase-binding peptide motifs, which is a different mode of operation, function and effect from the Inventions of Groups III, IV, VI-X, which are directed to *use* of the identified kinase-binding peptide motifs.

Inventions of Groups IV and VII and the Inventions of Groups III, VI, VIII-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as

capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the methods of treatment of Groups IV and VII take place in a living creature with multiple organ systems, in order to reverse the metabolic processes of diseases, so as to result in the cure or management of diseases, which are different modes of operation, functions and effects from the methods of inhibiting phosphorylation by kinases, validating a kinase as a target by determining the effect of binding on a biological sample, inhibiting transcription, or competing a known kinase inhibitor with a candidate kinase inhibitor, as in the methods of Groups III, VI, VIII-X.

Inventions of Group III and the Inventions of Group VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the peptides used in the method of Group III contain a phosphorylatable amino acid and so operate with molecules that have different molecular structures from the non-phosphorylatable peptides used in the method of Group VI.

Inventions of Group III and the Inventions of Groups VIII, X are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as

claimed because the methods for validating a kinase as a target by determining the effect of binding on a biological sample, inhibiting transcription, or competing a known kinase inhibitor with a candidate kinase inhibitor do not require for patentability the particulars of the methods for inhibiting kinases of the subcombination. The subcombination has separate utility such as in enzymologically characterizing a given kinase using an inhibitor.

Inventions of Group VI and the Inventions of Groups IX are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the methods for validating a kinase as a target by determining the effect of binding on a biological sample, inhibiting transcription, or competing a known kinase inhibitor with a candidate kinase inhibitor do not require for patentability the particulars of the methods for inhibiting kinases of the subcombination. The subcombination has separate utility such as in enzymologically characterizing a given kinase using an inhibitor.

Inventions of Group VIII and the Invention of Group X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the method of Group VIII, drawn

to validating a kinase as a target by determining the effect of binding on a biological sample, is a different function and effect from the method of competing a known kinase inhibitor with a candidate kinase inhibitor of Group X.

4. Because these inventions are distinct for the reasons given above and the amino acid sequence and literature searches required for each Groups is not required for each of the other Groups, one from the other, restriction for examination purposes as indicated is proper.

5. This application contains claims directed to the following patentably distinct species of the claimed invention: Kinases are identified at p. 1 of the specification that are Tyr, ZAP-70, ITK and Lck kinases.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 21, 26, 30, 38, 39, 42, and 60 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a *listing of all claims readable thereon, including any claims subsequently added.* An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other invention.

6. This application contains claims directed to the following patentably distinct species of the claimed invention: Peptides comprising a single non-degenerate phosphorylatable amino acid in a fixed position that is **Tyr**; peptides comprising a single non-degenerate phosphorylatable amino acid in a fixed position that is **Ser**; peptides comprising a single non-degenerate phosphorylatable amino acid in a fixed position that is **Thr**.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 2, 3, 9, 13, 42, 60 and 64 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a *listing of all claims readable thereon, including any claims subsequently added.* An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other invention.

7. This application contains claims directed to the following patentably distinct species of the claimed invention: Peptides comprising the formula: $(Xaa)_n$-Zaa-$(Xaa)_m$, where n and m are integers from 1-10 inclusive.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed value from 1-10 inclusive for **n** and **m** for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim **2** is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other invention.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Shibuya whose telephone number is (571) 272-0806. The examiner can normally be reached on M-F, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark Shibuya
Examiner
Art Unit 1639

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